

ARABELLA[®]



Active Nasal CPAP System for Infants Operator's Manual

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HAMILTON
MEDICAL
MAKING TECHNOLOGY SERVE MANKIND

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HAMILTON MEDICAL will make available on request circuit diagrams, component parts lists, descriptions, calibration instructions, or other information that will assist the user's appropriately trained personnel to repair those parts of the equipment designated by HAMILTON MEDICAL to be repairable.

Manufacturer

HAMILTON MEDICAL AG
Via Nova
CH-7403 Rhäzüns
Switzerland
Phone: (+41) 81 660 60 10
Fax: (+41) 81 660 60 20
www.hamilton-medical.com
ms@hamilton-medical.ch

In USA

HAMILTON MEDICAL Inc.
505 Edison Way
P.O. Box 30008
Reno, NV 89520
Phone: (775) 858-3200
Toll-free: (800) HAM-MED 1
or (800) 426-6331
Fax: (775) 856-5621
customer_service@hammed1.com

**Authorized representative
according to MDD**

HAMILTON Deutschland GmbH
Daimlerweg 5a
D-64293 Darmstadt
Germany
Phone: (+49) 6151 66 707-0
Fax: (+49) 6151 66 707-77

Definitions

WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTE:

Emphasizes information of particular importance.



Refer to the operator's manual for complete information.

General warnings, cautions, and notes

Intended use

- The ARABELLA is an active nasal CPAP device intended to support spontaneous breathing of infants, including those with very low birth weight.
- The ARABELLA system is intended for use by properly trained personnel under the direct supervision of a licensed physician.
In the USA, federal law restricts this device to sale by or on the order of a physician.
- Familiarize yourself with this operator's manual before using the Monitoring Gas Mixer on a patient.
- The ARABELLA is not an apnea monitoring device, nor is it intended to mechanically ventilate patients.

Monitoring and alarms

- Patients on the ARABELLA should be appropriately monitored by competent medical personnel and suitable monitoring devices.
- Make sure the audible alarm is not silenced before leaving the patient unattended.
- Be aware that if there is a power failure to the ARABELLA Monitoring Gas Mixer, the displays and alarms are not operational.

Fire and other hazards

- To reduce the risk of fire or explosion, do not place the ARABELLA system in a combustible or explosive environment. Do not use it with flammable anesthetic agents. Do not use it with any equipment contaminated with oil or grease.
- To reduce the risk of fire, do not use oxygen hoses that are worn or contaminated with combustible materials like grease or oil.
- In case of fire, immediately secure the patient's ventilatory needs, switch off the ARABELLA Monitoring Gas Mixer, and disconnect it from its gas and electrical sources.

Service and testing

- To ensure proper servicing and to prevent possible physical injury, only qualified personnel should attempt to service the ARABELLA.
- To reduce the risk of electrical shock, do not remove the Monitoring Gas Mixer housing. Refer the device for servicing by qualified personnel.
- To reduce the risk of electrical shock, disconnect electrical power from the Monitoring Gas Mixer before servicing.
- Do not attempt service procedures other than those specified in the service manual.
- Use replacement parts supplied by HAMILTON MEDICAL only.

-
- Any attempt to modify the ARABELLA hardware or software without the express written approval of HAMILTON MEDICAL automatically voids all warranties and liabilities.
 - The preventive maintenance program requires a general service at least once a year.
 - To ensure the device's safe operation, always run the prescribed tests and calibrations before using the ARABELLA on a patient. If the ARABELLA fails any tests, remove it from service immediately. Do not use the ARABELLA until necessary repairs are completed and all tests passed.

Electromagnetic compatibility

The ARABELLA system complies with the IEC 60601-1-2:1993 EMC (Electro Magnetic Compatibility) Collateral Standard. Certain transmitting devices (for example, cellular phones, walkie-talkies, cordless phones, paging transmitters), however, emit radio frequencies that could interrupt ARABELLA system operation. Do not operate these transmitting devices within the vicinity of the ARABELLA system. Do not use the ARABELLA system in an environment with magnetic resonance imaging (MRI) equipment.

Section 4 lists the alarms that can possibly occur due to such disruption, along with the corresponding corrective actions. Consult your service representative in case of interrupted device operation.

Units of measure

- Pressures are indicated on the ARABELLA in cmH_2O . Millibars (mbar) or hectoPascals (hPa) are used by some institutions instead of cmH_2O . Since 1 mbar equals 1 hPa, which equals 1.016 cmH_2O , the units may be used interchangeably.
- Flow is indicated on the ARABELLA in LPM (liters per minute).

Disposal

Dispose of all parts removed from the device according to your institution's protocol. Follow applicable regulations regarding disposal or recycling.

Year of manufacture

The year of manufacture can be determined from the serial number label, which is on the ARABELLA Monitoring Gas Mixer back panel. The first two digits of the part number are the last two digits of the year of manufacture.

Software version

The software version for the ARABELLA Monitoring Gas Mixer is visible during power-up. To view it, switch on power to the Monitoring Gas Mixer. The Oxygen window displays "888", then the software version, followed by the oxygen percentage.

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1 General information

1.1 Introduction

The ARABELLA system provides safe, effective delivery of NCPAP to infants, including those with very low birth weight (VLBW). The system includes the Monitoring Gas Mixer device along with a Universal Generator, Delivery Circuit, and Cap for single-patient use.

The Monitoring Gas Mixer incorporates a blender, oxygen analyzer, graduated flowmeter, and an alarm system. A 50-psi outlet for an additional flowmeter lets you deliver flow via a low-flow cannula, manual resuscitator, or for nebulizer therapy.

1.2 Functional description of Monitoring Gas Mixer

The Monitoring Gas Mixer is the controller for the inspired gas source and the monitor for the system. It precisely mixes air and oxygen to the set oxygen percentage, and it controls the flow of mixed gas to the Delivery Circuit through a separate humidification system. For patient safety, the Monitoring Gas Mixer has a digital manometer-type pressure gauge with integrated high and low pressure alarms. It also has a pressure relief system for overpressure protection. The Monitoring Gas Mixer provides an oxygen analyzer with integrated high and low oxygen alarms.

Appendix B includes a diagram of the ARABELLA's pneumatic system.

1.3 Concept and basic principles

Continuous positive airway pressure (CPAP) was first introduced in the 1930s as "continuous distending pressure," and was used as a treatment for pulmonary edema and asthma. It was rapidly replaced as mechanical ventilation became a reliable modality. In 1968, Gregory and associates reintroduced continuous distending pressure therapy for newborn respiratory distress syndrome and renamed it CPAP. In the late 1980s, reports suggested that the use of nasal CPAP without intubation could produce excellent results and reduce the incidence of chronic lung diseases.¹

The purpose of CPAP therapy is to improve compliance, maintain lung volume, and reduce the work of breathing while providing an adequate oxygen supply. Iatrogenic effects such as further lung damage and long term morbidity could be minimized as well.² In general, CPAP has two categories for use: as a therapeutic modality or as a supportive modality. Some situations may combine both.

CPAP may be indicated in these neonatal and pediatric situations:

Therapeutic	Supportive	Combined therapeutic and supportive
Respiratory distress syndrome	Apnea with prematurity	Weaning from mechanical ventilation
Pulmonary edema	Tracheal malacia	
Pneumonia with respiratory failure	Transient tachypnea	
Atelectasis		

1. Avery, M. et al: Is Chronic Lung Disease in Low Birthweight Infants Preventable? A Survey of 8 Centers. *Pediatrics* 1987;79:26-30

2. Klausner, J. Hutchinson, A.: Decreased Imposed Work With a New Nasal Continuous Positive Airway Pressure Device. *Pediatric Pulmonology* 1996; 22: 188-194.

Although nasal CPAP (NCPAP) should save many infants from intubation and mechanical ventilation, conventional NCPAP has been less successful due to an inability to maintain a proper seal at the infants nares and high imposed work of breathing. Many cases of failed NCPAP are more closely related to the devices used for delivery than by the infant's inability to breathe spontaneously.

The ARABELLA system is a unique technology designed for the delivery of NCPAP to the neonate through its nasal cannula. Utilizing a twin jet effect, a fluidics principle of gas flow designed to decrease the work of breathing, the ARABELLA system provides safe, effective delivery of NCPAP to infants, including very low birth weight (VLBW) infants. The advantages of this system are no moving parts, small size, minimum deadspace, quiet operation and decreased resistance to respiration. During treatment with NCPAP, optimal re-expansion of lung units with minimal work of breathing is best accomplished when the airway pressure is maintained at a constant desired NCPAP level throughout the entire breathing cycle. To achieve this, the ARABELLA system provides a continuous jet of fresh gas close to the nasal airway.

The ARABELLA system is integrated with a nasal cannula with interchangeable silicone prongs (size marked), a Delivery Circuit (heated wire), Cap, and the Monitoring Gas Mixer. HAMILTON MEDICAL has designed all components of the ARABELLA system to operate as a unit. All safety tests and therapeutic effectiveness data are based on the use of the complete system.

The ARABELLA dynamic fluidic cycling system requires up to approximately 110 cmH₂O driving pressure to operate properly. This is well beyond the operating pressure of a standard ventilator and requires a special overpressure safety feature not available on infant ventilators. The Monitoring Gas Mixer provides precise control of flow, pressure, and FiO₂ for safety and effectiveness. The integral monitoring system and special alarms are built-in to ensure the highest level of patient safety.

1.4 Physical description

1.4.1 Delivery Circuit and accessories

Figure 1-1 shows the ARABELLA with its Delivery Circuit and accessories. A cap is also used; it is not shown.

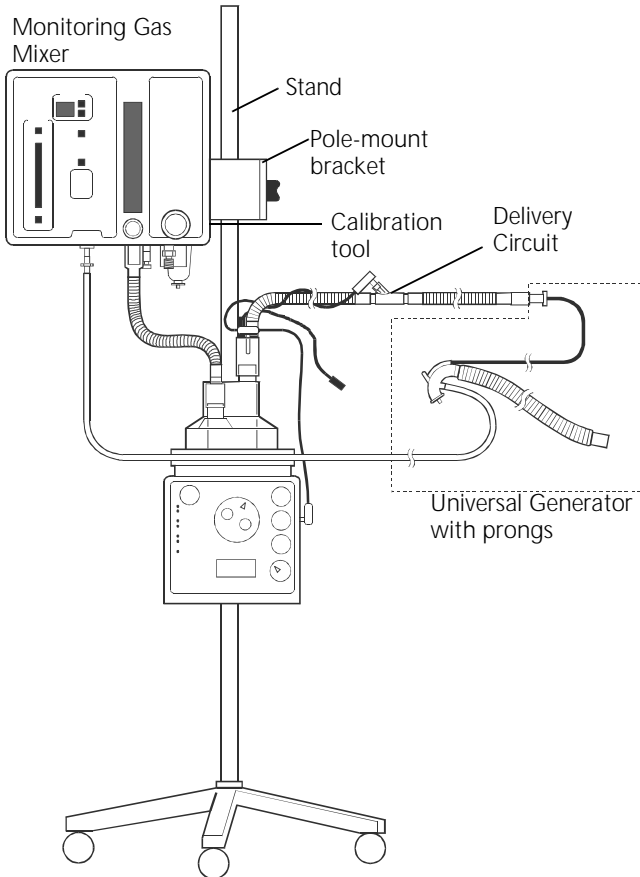


Figure 1-1. ARABELLA system

1.4.2 Monitoring Gas Mixer

Figure 1-2 through Figure 1-7 show the controls, indicators, and other important parts of the Monitoring Gas Mixer.

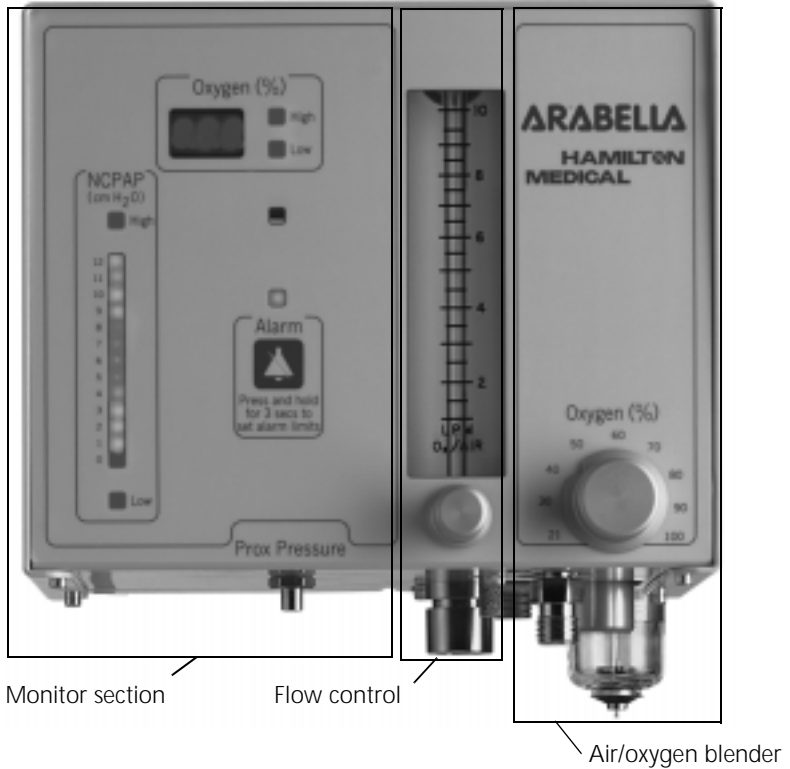


Figure 1-2. Monitoring Gas Mixer front panel

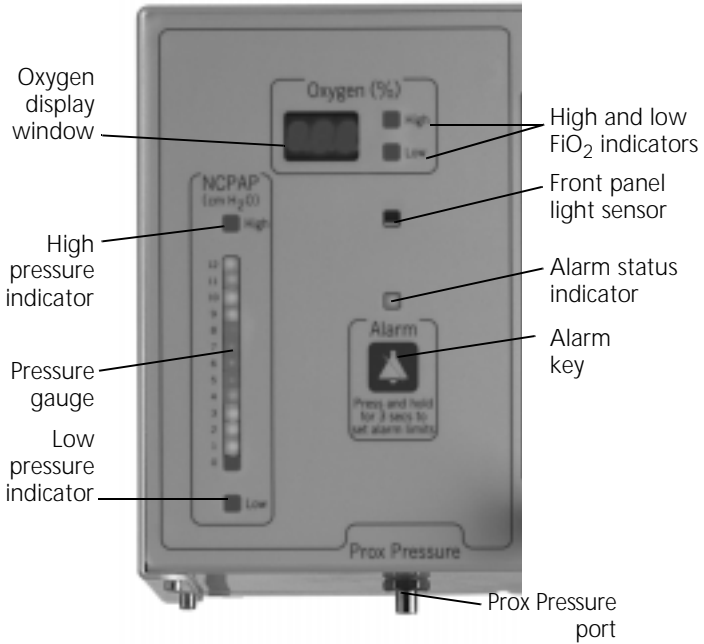


Figure 1-3. Monitor section

Item	Description
Oxygen display window	Displays monitored oxygen concentration. On start-up, the window displays 888 for 1 s, followed by the software version of the system for 1 s, before the measured oxygen concentration is displayed.
High and Low FiO ₂ indicators (red)	Light when oxygen alarm limits are set or violated.
Front panel light sensor	Adjusts the brightness of the front panel indicators, based on changes in ambient light.
Alarm status indicator (green)	Changes from flashing to steady when the alarms are enabled.
Alarm key	Sets alarm limits or resets/silences alarms.

Item	Description										
Prox Pressure port	Connects the proximal pressure line of the Universal Generator.										
High and Low pressure indicators (red)	Light when pressure alarm limits are set or violated.										
Pressure gauge	<p>A digital bar-graph type gauge, which displays proximal pressure in cmH₂O. Uses color to display operational ranges, as follows:</p> <table border="0"> <thead> <tr> <th data-bbox="404 496 468 520">Color</th> <th data-bbox="507 496 703 520">Pressure (cmH₂O)</th> </tr> </thead> <tbody> <tr> <td data-bbox="404 533 443 557">Red</td> <td data-bbox="507 533 524 557">0</td> </tr> <tr> <td data-bbox="404 560 471 584">Yellow</td> <td data-bbox="507 560 557 584">1 - 3</td> </tr> <tr> <td data-bbox="404 587 468 611">Green</td> <td data-bbox="507 587 557 611">4 - 8</td> </tr> <tr> <td data-bbox="404 614 471 638">Yellow</td> <td data-bbox="507 614 568 638">9 - 12</td> </tr> </tbody> </table>	Color	Pressure (cmH₂O)	Red	0	Yellow	1 - 3	Green	4 - 8	Yellow	9 - 12
Color	Pressure (cmH₂O)										
Red	0										
Yellow	1 - 3										
Green	4 - 8										
Yellow	9 - 12										

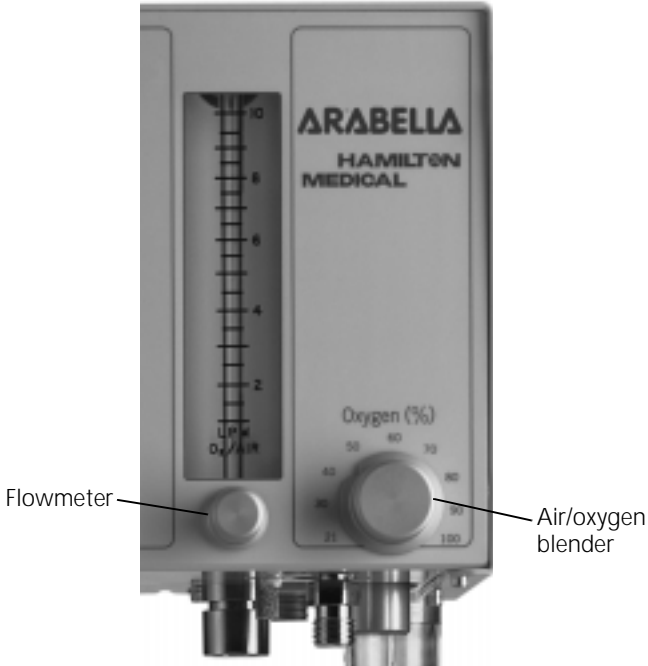


Figure 1-4. Flow control section and air/oxygen blender

Item	Description
Flowmeter	<p>A non-back pressure compensated flowmeter, which sets and displays mixed gas flow delivery. Turning the knob counterclockwise activates the flow. The set flow rate determines the NCPAP level. Ideally, if the correct prongs size is used, a setting of 8 l/min should result in a pressure level of +5 cmH₂O of NCPAP.</p> <hr/> <p>NOTE:</p> <p>It is recommended that you check the required flow to achieve the desired pressure before you place the prongs in the infant's nares (Section 3.5).</p> <hr/>
Oxygen (%) knob (air/oxygen blender)	Sets oxygen percentage in delivered gas

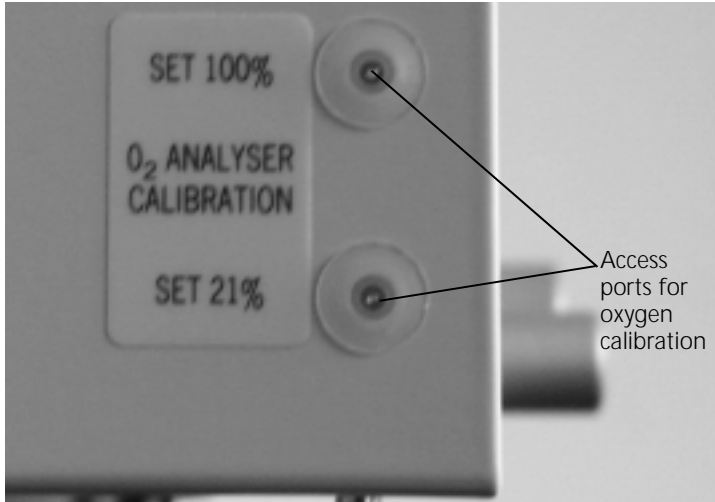


Figure 1-5. Left side panel

Item	Description
O ₂ ANALYSER CALIBRATION - SET 100% and SET 21%	Ports that permit access to oxygen calibration potentiometers (see Section 4.3).

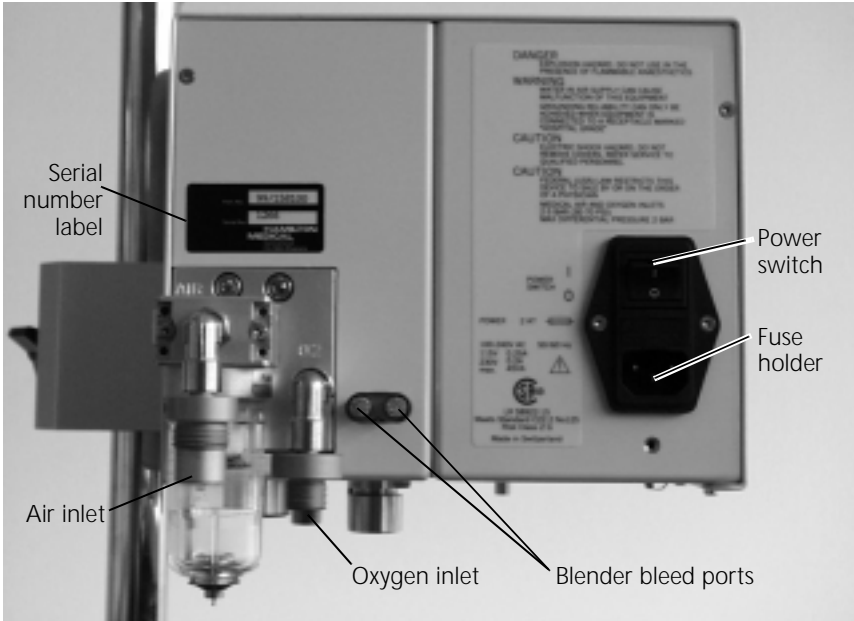


Figure 1-6. Monitoring Gas Mixer rear panel

Item	Description
Power switch	Toggle-type
Fuse holder	Holds two fuses, 2 A, 250 V, type T (slow breaking), H (high current capacity)
Blender bleed ports	Sintered brass
Oxygen inlet	Male DISS fitting

Item	Description
Air inlet	<hr/> <p>NOTE:</p> <p>Use only clean, dry medical-grade oxygen and air with this device to prevent harm to the patient or damage to the Monitoring Gas Mixer. Check for water or particulate matter trapped in the gas supply filter before each use.</p> <hr/> <p>5-μm (micron) inlet filter and water trap with manual drain. Male DISS fitting.</p>
Serial number label	Shows part number and serial number. The first two digits of the part number are the last two digits of the year of manufacture.

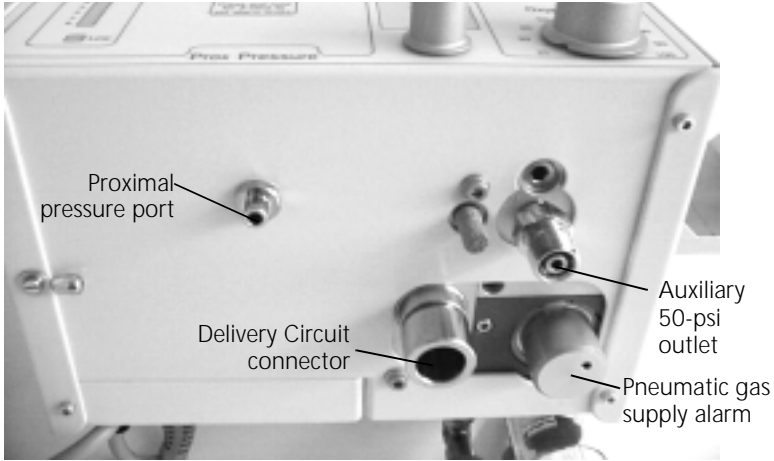








Figure 1-7. Base of Monitoring Gas Mixer

Item	Description
Prox Pressure (proximal pressure) port	Connects Delivery Circuit proximal pressure line
Delivery Circuit connector	A 15-mm ID connector, which connects Delivery Circuit
Auxiliary outlet	A port with check valve, which permits delivery of blended gases via a supplemental flowmeter
Pneumatic gas supply alarm	Causes an audible alarm if either gas source (air or oxygen) varies more than 200 kPa (30 psi) from the other gas source. The Monitoring Gas Mixer begins to operate from the gas with the higher pressure. Restoring the gas pressure silences the alarm.

1.5 Symbols and abbreviations

Table 1-1. Back panel symbols

	Power switch positions. "I" represents the on position; "O" represents the off position.
	Fuse, 2 A, 250 V, type T (slow-breaking), H (high current capacity)
	Classification of Medical Electrical Equipment, type B, as specified by IEC 60601-1:1988
	Refer to the operator's manual for complete information
	CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Council Directive 93/42/EEC concerning medical devices
	Canadian Standards Association and National Recognized Test Laboratory approval

2 Preparing for operation

This section describes how to set up the ARABELLA for operation before putting it on a patient.

NOTE:

Before using the Monitoring Gas Mixer for the first time, HAMILTON MEDICAL recommends that you clean its exterior as described in Section 6.

2.1 Connecting to ac power

WARNING

To minimize the risk of electrical shock, plug the Monitoring Gas Mixer power cord into a grounded ac power receptacle. To ensure grounding reliability, use a special hospital-grade receptacle.

NOTE:

To prevent unintentional disconnection of the power cord, make sure the cord is secured with the power cord clip.

Connect the Monitoring Gas Mixer to a grounded ac outlet. Always check for the reliability of the ac outlet.

2.2 Connecting the gas supplies

WARNING

To minimize the risk of fire, do not use oxygen hoses that are worn or contaminated with combustible materials like grease or oil.

CAUTION

To prevent damage to the unit, connect only clean, dry medical-grade gases. Check for water and particle build-up in the gas supply water trap before each use.

NOTE:

When using oxygen cylinders with the ARABELLA, it is recommended that you use pressure-reducing valves with fittings identical to those on the wall supply. This allows a seamless switchover if the cylinders become depleted.

The ARABELLA uses compressed air and oxygen with pressures between 207 to 483 kPa (2 to 4.83 bar, 30 to 70 psi). It has DISS male gas fittings.

The compressed gases can come from central gas supplies, from gas cylinders, or from the VENTILAIR^{II} Compressor.

Connect the air and oxygen hoses to the Monitoring Gas Mixer inlet fittings, shown in Figure 2-1.



Figure 2-1. Connecting the air and oxygen supplies

2.3 Installing the humidifier

Install a humidifier to the ARABELLA stand using the C-clamp. The humidification systems listed in Appendix E are compatible with the ARABELLA system heated-wire Delivery Circuits.

Prepare the humidifier as described in the manufacturer's operation manual.

NOTE:

- *Always* fill the humidifier chamber with sterile water before turning on the gas flow or the humidifier heater.
 - For the Monitoring Gas Mixer fluidics to function properly, a driving pressure up to approximately 110 cmH₂O is required. In some instances, it may be necessary to pressurize the water bag for a continuous-feed humidification system to prevent back pressure to the water supply.
-

2.4 Installing the Delivery Circuit

WARNING

Improper assembly of the ARABELLA Delivery Circuit may result in rebreathing.

NOTE:

- If water accumulates in the Delivery Circuit, consult the humidifier operator's manual for correct settings of temperature and relative humidity.
 - The heater wire from the Delivery Circuit should fit easily into the heater adapter cable that is supplied with the individual manufacturer's humidifier systems. If the wire does not fit easily, *do not force it*.
-

Assemble the Delivery Circuit parts as shown in Figure 2-2 (the Fisher & Paykel humidifier is shown). Follow the specific guidelines for the different parts.

1. Connect the short Delivery Circuit hose between the Monitoring Gas Mixer and humidifier inlet. (The 15-mm adapter end of the short corrugated tube connects into the device outlet in the base of the Monitoring Gas Mixer. The other end connects to the humidifier inlet. Adapters are

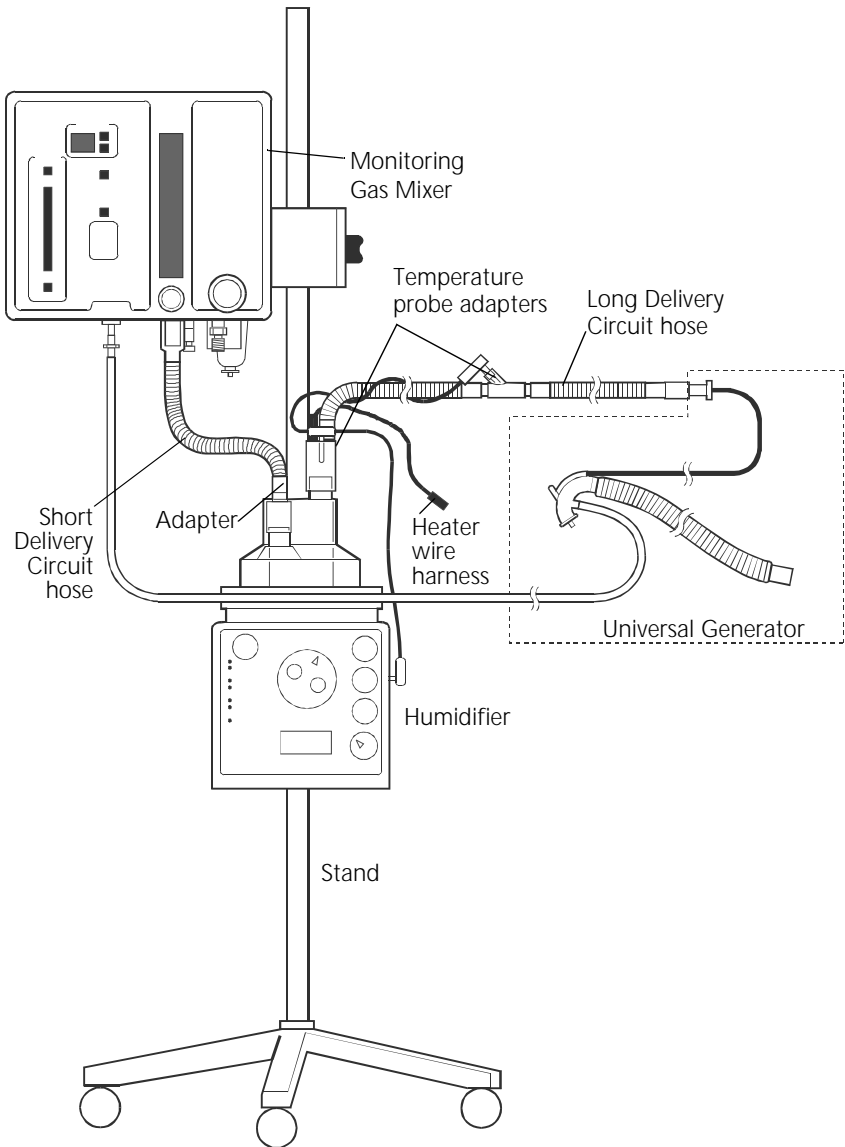


Figure 2-2. Installing the Delivery Circuit

included in each Delivery Circuit package to attach to various humidifiers.)

2. Connect the long (heated-wire) Delivery Circuit hose:
 - a. Connect one end to the humidifier outlet.
 - b. Insert the temperature probes into the adapters in the hose.
 - c. Connect the heater wire harness from the hose to the humidifier.

2.5 Running preoperational tests

Run the required tests and calibrations (Table 4-1). (If you are using the ARABELLA on a new patient, run the oxygen analyzer test and blender alarm test now. You will run the pressure gauge test later.)

NOTE:

To ensure the safe operation of the ARABELLA, always run the prescribed tests and calibrations before using the unit on a patient. If the unit fails any tests, remove it from clinical use immediately. Do not use the ARABELLA until necessary repairs are completed and all tests passed.

3 Operating instructions

After the ARABELLA is set up as described in Section 2, follow these instructions to prepare the patient and to operate the unit.

3.1 Attaching the Cap

1. Select the appropriate size Cap. Although the infant's head size does not always correspond to the infant's weight, these guidelines will help you select the proper size Cap:

Size	Weight
1 (S)	450 to 750 grams
2 (M)	650 to 900 grams
3 (L)	900 to 1600 grams
4 (XL)	1500 to 2500 grams
5 (XXL)	> 2500 grams

WARNING

A properly fitting Cap is essential to maintaining the placement of the prongs. A Cap that is too large will have a tendency to slide down over the infant's forehead and into the eyes. A Cap that is too small will slide off the back of the head and pull the nasal prongs too far into the infant's nose. As with the nasal prongs, it is necessary to monitor the infant's growth to determine when a larger size Cap may be appropriate.

2. Gently pull the Cap over the infant's head, making sure the two ties are at the top of the head in alignment with the bridge of the infant's nose (Figure 3-1). Make sure the infant's ears are flat against the head inside the Cap, and pull the front of the Cap to the eyebrows. The back of the Cap should cover the nape of the infant's neck. The Cap should comfortably cover the infant's head entirely.



Figure 3-1. Positioning the Cap

NOTE:

The Cap may have sections trimmed away to expose portions of the infant's scalp for observation or for exposure of an IV site.

3.2 Attaching the Universal Generator set

1. Attach the Universal Generator set to the Delivery Circuit (Figure 3-2). The clear proximal pressure line goes to the Monitoring Gas Mixer Prox Pressure port. The blue tube with adapter goes to the tube with heated wire.

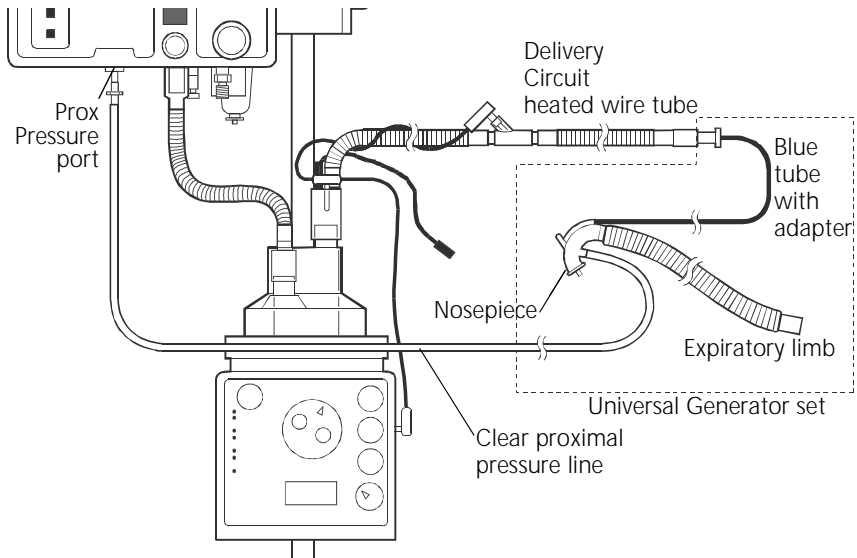


Figure 3-2. Connecting the Universal Generator set

2. Stretch the compressed expiratory limb until it is fully extended (Figure 3-3).

NOTE:

- Make sure the expiratory limb is fully extended before NCPAP delivery. This extended limb diverts the NCPAP gas flow away from the infant's head.
 - There are small perforations in the expiratory limb at the point of attachment to the Generator, in the central section, and at the dorsal end. These are vent ports so gas can escape if the expiratory limb becomes occluded.
-

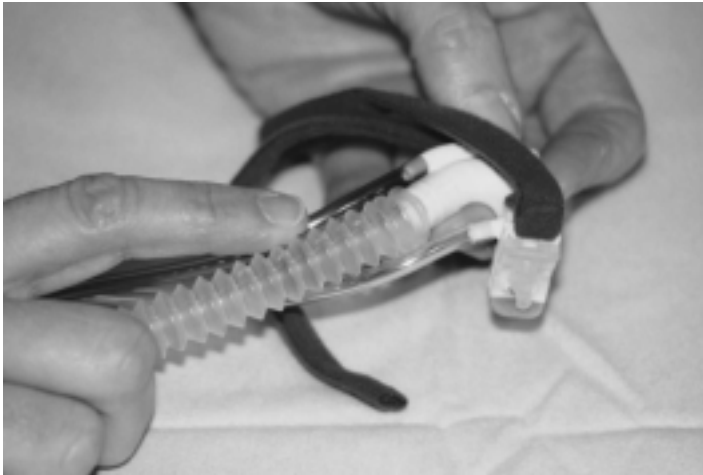


Figure 3-3. Expiratory limb

3.3 Selecting prongs

1. Select the appropriate size prongs using the KNOSOMETER™ guide provided (Figure 3-4).



Figure 3-4. Using the KNOSOMETER to determine prong size

WARNING

To maintain proper NCPAP levels and to avoid forcing the prongs too far into the infant's nose, choose the largest size prong that will comfortably fit the infant's nares. Re-evaluate proper prong size as the infant's nasal mucosa shrinks, or in the case of long-term use, as the infant continues to grow.

2. Place the correct size prongs into the white Generator nosepiece (Figure 3-5). Make sure the soft silicone prongs are properly placed and securely seated.



Figure 3-5. Seating prongs into the Generator nosepiece

3.4 Pressure functional test

NOTE:

The functional tests must be performed before you connect a patient to the ARABELLA system. If the system fails any of the prescribed tests, remove it from service immediately. Do not return the system to clinical service until any necessary repairs have been completed and all functional tests have been successfully completed.

Perform the pressure functional test. This test verifies the proper flow-to-pressure ratio of the ARABELLA system. Perform this test before placing a new patient on the ARABELLA.

1. Set up the ARABELLA as for patient use, including Delivery Circuit, Universal Generator with prongs, and humidification system.
2. Make sure the ARABELLA Monitoring Gas Mixer is connected to oxygen and air sources and the unit is powered on.
3. Turn the flowmeter control knob counterclockwise to achieve 8 l/min gas flow.
4. Set the Oxygen to the desired value.
5. Occlude the prongs, and VERIFY that the pressure gauge reads 5 cmH₂O. (Refer to the Pressure-flow nomogram in Appendix C.) An increase in flow should result in an increase in NCPAP pressure. A decrease in flow should result in a decrease in NCPAP pressure.
6. Turn the flowmeter control knob counterclockwise until the pressure gauge reads 11 cmH₂O.
7. VERIFY that the pressure is released and that the gauge now reads 0 cmH₂O. You will hear a clicking as the overpressure valve opens. After 3 s, the ARABELLA will attempt to re-establish pressure.

8. Release the prongs.
9. VERIFY that the pressure drops to +0 cmH₂O (or +1 cmH₂O, when small prongs are used).

If the NCPAP gauge does not register pressure, make sure the clear, proximal pressure line from the Generator/prongs is connected to the Prox Pressure port at the base of the Monitoring Gas Mixer; then re-establish flow.

If the pressure reading does not reflect the changes in flow, and a complete check of the Delivery Circuit and humidifier verifies that there is no occlusion or air leak in the circuit, replace the Generator or Delivery Circuit. Then repeat the procedure above. If the test still does not pass, have the Monitoring Gas Mixer serviced.

If the overpressure valve does not release pressure, have the Monitoring Gas Mixer serviced.

3.5 Starting NCPAP

NOTE:

Make sure the humidifier chamber is filled with sterile water before you turn on the gas flow or the humidifier heater.

1. Switch on power to the Monitoring Gas Mixer, if it is not already on.
2. Set the Oxygen control as desired.
3. Adjust flow to select the desired NCPAP level. Generally, a 5 cmH₂O NCPAP level is the nominal starting point. (Refer to the Pressure-Flow Nomogram in Appendix D.)
4. Gently insert the prongs into the infant's nares (Figure 3-6). Observe the pressure gauge.



Figure 3-6. Inserting the prongs into the infant's nares

5. Secure the clear proximal pressure line with the tan tie at the top of the Cap (Figure 3-7). Situate the prongs to avoid placing any pressure on the infant's nasal septum. The base of the prongs should *not* rest on the infant's nasal septum.

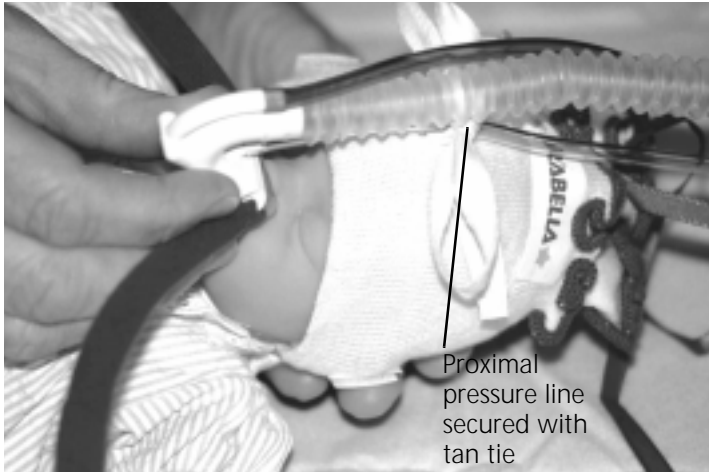


Figure 3-7. Proximal pressure line secured with tan tie

WARNING

Do not attach the blue gas delivery tubing to the Cap. This may decrease the maneuverability of the prongs when you reposition the infant and may force the prongs too far into the nares.

6. Attach the blue foam straps from the Generator/prongs to the Cap as follows. Open the VELCRO[®] tabs on either side of the Cap (Figure 3-8), and position the blue foam straps to the VELCRO. Close the tabs to secure the straps. The straps are *not* adjustable at the Generator connection.

WARNING

Never overtighten straps in an attempt to maintain a proper seal at the prongs. Always use larger size prongs. It is not necessary to pull the straps tightly across the infant's face in order to maintain the NCPAP level. If the proper size prongs are used, the infant's nose should not be forced into an unnatural position.

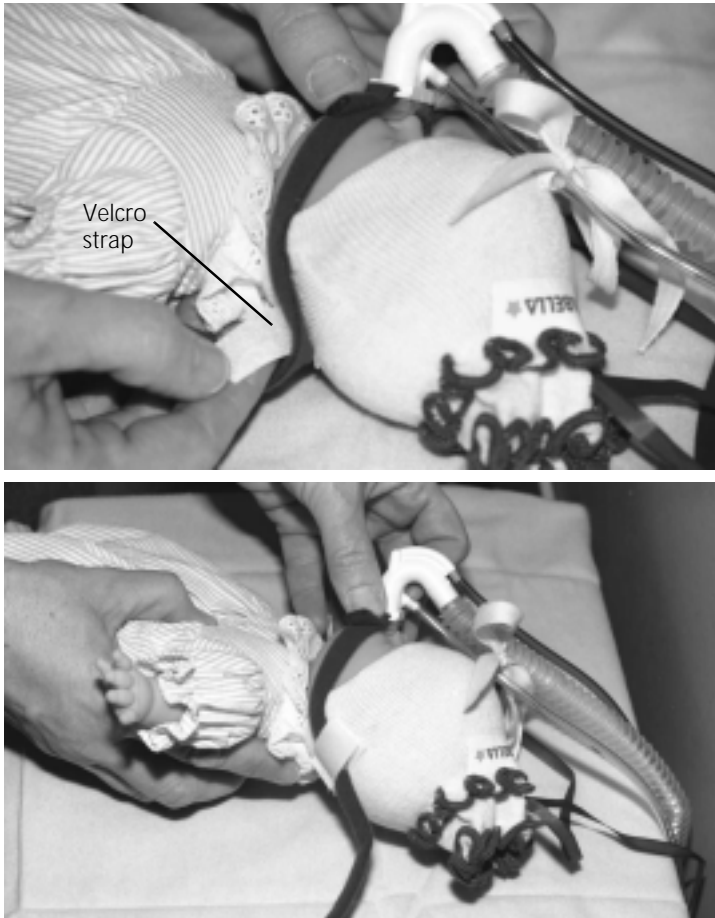


Figure 3-8. Attaching Generator/prongs to Cap

7. Secure the extended expiratory limb and the clear proximal pressure line to the back of the Cap with the colored tie. Position the expiratory limb to reduce any pressure on the nose and the septum (Figure 3-9).

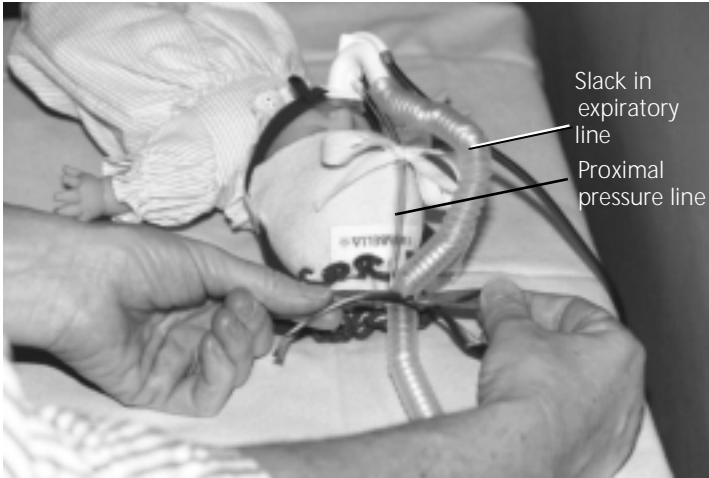


Figure 3-9. Securing tubing with colored tie

8. Verify that the humidifier is operating and the temperature is between 36 to 37 °C. The dynamic fluidic cycling pressure change has a cooling effect, which requires this temperature range to prevent drying of the nasal mucosa.

3.6 Setting alarms

NOTE:

The ARABELLA may not prevent an inadvertent control setting change. If the setting change is significant, however, an alarm will result.

1. Set the alarms by pressing and holding the Alarm key (Figure 3-10) for 3 s. (The alarm indicators flash and a series of beeps sound. A green status indicator above the alarm key changes from flashing to steady to indicate that the alarm system is enabled.) The alarm limits are set to the following values:
 - High pressure: Current pressure gauge reading + 3 cmH₂O
 - Low pressure: Current pressure gauge reading - 2 cmH₂O
 - High oxygen: Current oxygen analyzer reading + 5% of full scale, to a maximum of 103%
 - Low oxygen: Current oxygen analyzer reading - 5% of full scale, minimum 18%



Figure 3-10. Setting the alarms

For example, if the pressure gauge shows 5 cmH₂O, then the High pressure limit will be 8 cmH₂O and the Low pressure limit will be 3 cmH₂O.

NOTE:

- To prevent inappropriate alarms, readjust the alarm limits when you change the Oxygen or flow setting.
 - If you do not set the alarm limits, the Monitoring Gas Mixer automatically sets the alarms after 2 min after startup, according to the rules above.
 - There is a delay of 15 s from when the unit reaches the alarm setpoint until it activates the alarm (except in the case of a total loss of pressure, when there is no delay).
 - Make sure the audible alarm is enabled before leaving the patient unattended. The green status indicator atop the Alarm key should be steady, not flashing. You can silence an active audible alarm for 30 s. The gas source alarm cannot be silenced.
-

2. Respond to any alarms as described in Section 5.

4 Tests and calibrations

4.1 Introduction

The tests and calibrations described in this section help verify the safety and reliability of the ARABELLA. Perform the ARABELLA's tests and calibrations as described in Table 4-1, in the order given. If a test fails, troubleshoot the unit as indicated or have it serviced. Make sure the tests pass before you return the ARABELLA to clinical use.

Table 4-1. When to perform tests and calibrations

Perform in any of these cases	Test or calibration
Before placing a new patient on the ARABELLA	Oxygen analyzer functional test; oxygen analyzer calibration (if the oxygen analyzer functional test fails), blender alarm functional test; pressure functional test. <hr/> NOTE: To ensure the ARABELLA's safe operation, always run the prescribed tests and calibrations before using the unit on a patient. If the unit fails any tests, remove it from clinical use immediately. Do not use the ARABELLA until necessary repairs are completed and all tests passed. <hr/>
After installing a new oxygen cell	Oxygen analyzer calibration
Whenever monitored data is questionable	Any applicable test

4.2 Oxygen analyzer functional test

This test ensures the proper calibration and linearity of the analyzer in comparison to the oxygen blender. Perform the test before placing the ARABELLA on the patient.

1. Make sure the Monitoring Gas Mixer is connected to oxygen and air sources and the unit is powered on.
2. Turn the flowmeter control knob counterclockwise to achieve 5 to 6 l/min gas flow.
3. Set the Oxygen control to 21%. VERIFY that the Oxygen window reads 19 to 23%.
4. Set the Oxygen control to 100%. VERIFY that the Oxygen window reads 98 to 102%.
5. Set the Oxygen to 50%. VERIFY that the Oxygen window reads 48 to 52%.

If a reading is out of range, calibrate the oxygen analyzer (see Section 4.3).

4.3 Oxygen analyzer calibration

CAUTION

Adjust calibration potentiometers carefully. Using excessive force when aligning the tool (recessed end of tool works best) to adjust potentiometers could damage potentiometers. Damage to a potentiometer could cause inaccurate oxygen readings and the inability to calibrate the oxygen analyzer.

NOTE:

If the Monitoring Gas Mixer or oxygen cell was stored at lower than room temperature, allow it approximately 30 min to reach room temperature before calibration.

Perform this calibration if the oxygen analyzer calibration fails or after installing a new oxygen cell, as follows. It is not necessary to calibrate the oxygen analyzer before each use.

1. Make sure the Monitoring Gas Mixer is connected to oxygen and air sources and the unit is powered on.
2. Turn the flowmeter control knob counterclockwise to achieve at least 8 l/min gas flow.
3. Set the Oxygen control to 21%. Wait 1 min. VERIFY that the Oxygen window reads 21.

If the Oxygen window does not read 21%, pry off the plastic cover and gently adjust the lower (SET 21%) potentiometer (on left side panel of the Monitoring Gas Mixer) with the calibration tool provided or with a very small flathead screw, until the Oxygen window reads 21% (Figure 4-1).



Figure 4-1. Left side panel

4. Set the Oxygen control to 100%. Wait 1 min. Check the Oxygen reading.
If the Oxygen window does not read 100%, pry off the plastic cover and gently adjust the upper (SET 100%) potentiometer (on left side panel of the Monitoring Gas Mixer) with the calibration tool provided or with a very small flathead screw, until the Oxygen window reads 100% (Figure 4-1).
5. Disconnect the air supply. VERIFY that the Oxygen window reads 100% and that an Oxygen alarm is activated due to the large pressure differential between the two source gases. Reconnect the air supply.
6. Recheck the Oxygen window at 21% and at 100% three to four times, repeating step 3 through step 4 above, to verify proper linear calibration.
7. Set the Oxygen control to 50%. VERIFY that the Oxygen window reads 48 to 52%.
8. Set the Oxygen control to 100%. Disconnect the air supply. VERIFY that the Oxygen window reads 100%. Reconnect the air supply.
9. Set the oxygen control to 21%. Disconnect the oxygen supply. VERIFY that the Oxygen window reads 21%. Reconnect the oxygen supply.

NOTE:

When the oxygen cell is depleted, the alarm sounds continuously. The Monitoring Gas Mixer must have a functioning, calibrated oxygen cell in order to avoid a continuous audible oxygen alarm. A reading of less than 18% creates this alarm. To avoid depletion of the oxygen cell during use, HAMILTON MEDICAL recommends an annual change of the oxygen cell during preventive maintenance of the Monitoring Gas Mixer.

4.4 Blender alarm functional test

This test verifies that the blender alarm operates properly. Perform this test before placing a new patient on the ARABELLA.

1. Make sure the Monitoring Gas Mixer is powered on and the gases are disconnected.
2. Connect the ARABELLA to one gas source. VERIFY that a shrill alarm sounds.
3. Connect the ARABELLA to the other gas source, so both are connected. VERIFY that the alarm ceases.
4. Disconnect the ARABELLA from the first gas source. VERIFY that the alarm sounds again.

If the test fails, check the air water trap for any liquid or debris, as described in Section 6. (Contamination of the air source may cause failure of the Monitoring Gas Mixer.)

4.5 Pressure functional test

This test verifies the proper flow-to-pressure ratio of the ARABELLA system. Perform this test before placing a new patient on the ARABELLA.

1. Set up the ARABELLA as for patient use, including Delivery Circuit, Universal Generator with prongs, and humidification system.
2. Make sure the ARABELLA Monitoring Gas Mixer is connected to oxygen and air sources and the unit is powered on.
3. Turn the flowmeter control knob counterclockwise to achieve 8 l/min gas flow.
4. Set the Oxygen to the desired value.
5. Occlude the prongs, and VERIFY that the pressure gauge reads 5 cmH₂O. (Refer to the Pressure-flow nomogram in Appendix C.) An increase in flow should result in an

increase in NCPAP pressure. A decrease in flow should result in a decrease in NCPAP pressure.

6. Turn the flowmeter control knob counterclockwise until the pressure gauge reads 11 cmH₂O.
7. VERIFY that the pressure is released and that the gauge now reads 0 cmH₂O. You will hear a clicking as the overpressure valve opens. After 3 s, the ARABELLA will attempt to re-establish pressure.
8. Release the prongs.
9. VERIFY that the pressure drops to +0 cmH₂O (or +1 cmH₂O, when small prongs are used).

If the NCPAP gauge does not register pressure, make sure the clear, proximal pressure line from the Generator/prongs is connected to the Prox Pressure port at the base of the Monitoring Gas Mixer; then re-establish flow.

If the pressure reading does not reflect the changes in flow, and a complete check of the Delivery Circuit and humidifier verifies that there is no occlusion or air leak in the circuit, replace the Generator or Delivery Circuit. Then repeat the procedure above. If the test still does not pass, have the Monitoring Gas Mixer serviced.

If the overpressure valve does not release pressure, have the Monitoring Gas Mixer serviced.

5 Responding to alarms

Respond to an ARABELLA system alarm as follows:

1. Briefly press the Alarm key (Figure 5-1) to silence the audible alarm for 30 s. If the alarm condition persists, the audible alarm continues after 30 s.

NOTE:

If the monitored oxygen concentration or pressure drops below the allowed alarm limit ranges (see Appendix A), the alarm cannot be silenced.



Figure 5-1. Pressing the Alarm key

2. Readjust the alarm limits (see Section 3.6), as required. Correct the alarm condition as quickly as possible, referring to Table 5-1.

NOTE:

- As with all medical devices, prompt response to and immediate correction of all alarm conditions is recommended.
- Correct blender alarms immediately, as the selected oxygen concentration is not delivered during an alarm/bypass situation. During an alarm/bypass situation, the unit switches to operation from a single gas.
- The pressure gauge and pressure alarms are *not* enabled if the proximal pressure line of the Delivery Circuit is not connected to the Monitoring Gas Mixer and positive pressure is not applied to the Prox Pressure port at power on. This allows the Monitoring Gas Mixer to deliver analyzed, blended gas to other oxygen devices (oxygen hood, nasal cannula, etc.) without continuous audible pressure alarms.

Table 5-1. Troubleshooting alarms

Alarm indication	Meaning	Corrective actions
No pressure display	No pressure measurement <hr/> NOTE: If the proximal pressure tubing is not connected to the Prox Pressure port when the power is turned on, the pressure gauge is not enabled. This allows the Monitoring Gas Mixer to deliver analyzed, blended gas to other oxygen devices (oxygen hood, nasal cannula, etc.) without continuous audible pressure alarms.	Connect proximal pressure line to Prox Pressure port.

Table 5-1. Troubleshooting alarms (continued)

Alarm indication	Meaning	Corrective actions
Low NCPAP indicator lit, audible alarm	Low CPAP level. CPAP level \leq 2 cmH ₂ O below alarm setpoint or no pressure registers.	<ol style="list-style-type: none"> 1. Reposition prongs. 2. Check for disconnect or occlusion in Delivery Circuit. 3. Make sure prongs are large enough to prevent leak. 4. Reset alarm limits to reflect changed NCPAP setting. 5. Make sure flow setting is appropriate to deliver desired NCPAP. 6. Make sure prongs are attached properly to Generator. 7. Use pacifier to prevent infant from losing pressure from the mouth. 8. Have Monitoring Gas Mixer serviced.
High NCPAP indicator lit, audible alarm	High CPAP level or overpressure in the system. NCPAP \geq 3 cmH ₂ O above alarm setpoint.	<ol style="list-style-type: none"> 1. Check for occlusion or kink in expiratory limb. 2. Check Delivery Circuit for kinks or occlusion. 3. Check nasal prongs for mucous plug. 4. Reset alarm limits to reflect changed NCPAP setting. 5. Make sure flow setting is appropriate to deliver desired NCPAP.
Low Oxygen indicator lit, audible alarm	FIO ₂ too low for blender setting	<ol style="list-style-type: none"> 1. Reset alarm limits to reflect changed Oxygen setting. 2. Recalibrate oxygen analyzer. 3. Check for oxygen supply disconnect or pressure drop in oxygen supply. 4. Have oxygen cell replaced.

Table 5-1. Troubleshooting alarms (continued)

Alarm indication	Meaning	Corrective actions
High Oxygen indicator lit, audible alarm	FiO ₂ too high for blender setting	<ol style="list-style-type: none"> 1. Reset alarm limits to reflect changed Oxygen setting. 2. Recalibrate oxygen analyzer. 3. Check for air supply disconnect or pressure drop in air supply. 4. Have service replace oxygen cell. 5. Have service check for damage to potentiometer.
--- in Oxygen window, Low Oxygen indicator lit, audible alarm	Oxygen measurement \leq 18%. The alarm cannot be silenced.	<ol style="list-style-type: none"> 1. Reset alarm limits to reflect changed Oxygen setting. 2. Recalibrate oxygen analyzer. 3. Have oxygen cell replaced.
"Err" in Oxygen window, High Oxygen indicator lit, audible alarm	Oxygen measurement \geq 10% higher than oxygen setting	Recalibrate oxygen analyzer.
"Err" in Oxygen window, Low Oxygen indicator lit, audible alarm	Oxygen measurement \leq 10% lower than oxygen setting	Recalibrate oxygen analyzer.
No pressure reading, NCPAP High indicator lit, and audible alarm	Pressure > 11 cmH ₂ O (preset limit)	<ol style="list-style-type: none"> 1. Check for occlusion or kink in proximal pressure line. 2. Check for occlusion or kink in expiratory limb.
--- in Oxygen window, High and Low indicators lit, audible alarm	Oxygen cell exhausted or other technical failure	Have Monitoring Gas Mixer serviced.

Table 5-1. Troubleshooting alarms (continued)

Alarm indication	Meaning	Corrective actions
No audible alarm, no visual displays	Power failure or other technical failure in Monitoring Gas Mixer	<ol style="list-style-type: none">1. Check hospital ac power. When power returns, reset alarms. Verify control settings.2. Switch on power to Monitoring Gas Mixer.3. Have Monitoring Gas Mixer serviced.
The Alarm key fails to set the alarms	Hardware problem	Have Monitoring Gas Mixer serviced.

6 Cleaning and maintenance

6.1 Cleaning

WARNING

The Delivery Circuit, Cap, Generator, and prongs are *single-patient, single-use* items. Sterilization and reuse of the Delivery Circuit, Generator, or prongs may result in injury or death to operators, patients, or bystanders.

CAUTION

- To prevent damage to the Monitoring Gas Mixer exterior surfaces, do not use agents that contain abrasives or acetone.
 - To prevent damage to the Monitoring Gas Mixer labels, do not use alcohol to wipe the exterior surfaces.
 - To prevent damage to the Monitoring Gas Mixer, do not immerse any part of it, and do not gas- or steam-sterilize it.
 - To prevent damage to the Universal Generator, do not immerse any part of it and do not steam-sterilize it. The injector jets in the Universal Generator are not compatible with, and may be damaged by, heat, liquid, or ETO sterilization agents.
-

Wipe the exterior surfaces of the Monitoring Gas Mixer, stand, gas supply hoses, and power cord with an appropriate bactericidal agent, such as a buffered glutaraldehyde, after each patient use.

6.2 Preventive maintenance

Perform preventive maintenance on your ARABELLA according to the schedule in Table 6-1.

NOTE:

- HAMILTON MEDICAL recommends that you document all maintenance procedures.
 - Dispose of all parts removed from the device according to your institution's protocol. Follow applicable regulations regarding disposal or recycling.
 - Do not use a Monitoring Gas Mixer that needs recalibration, service, or repair until the necessary procedures are performed and the equipment has been tested to make sure it functions correctly.
-

Table 6-1. Preventive maintenance schedule

Interval	Part/accessory	Procedure
Between patients and according to your hospital's protocol	Delivery Circuit, Universal Generator, prongs, and Cap	Replace with new parts.
	Entire unit	Perform functional tests (Section 4).
Every day or as required	Delivery Circuit	Empty any water.
	Gas inlet water trap	Empty any water by pressing the manual drain on the bottom. To remove particulate debris, disconnect the hose from the gas supply and unscrew the clear plastic bowl. Take care not to dislodge the sealing O-ring from inside the water trap. Contact service if you notice excess water or debris in the air water trap.

Table 6-1. Preventive maintenance schedule (continued)

Interval	Part/accessory	Procedure
Every day or as required (continued)	Cap	Remove Cap and inspect infant's head (for example, for molding). Replace Cap with a larger size if required.
	Prongs	Inspect infant's nares and re-evaluate size. Install larger prongs if required.
Every 12 months	Entire unit	Have preventive maintenance kit installed; this includes replacement of the oxygen cell and other parts, followed by calibration and testing. This must be done by a qualified service technician according to instructions in the service manual.
As required	Mains fuses	<p>WARNING</p> <ul style="list-style-type: none"> • To reduce the risk of electrical shock, disconnect the electrical power from the device before removing a fuse. • For continued protection against a fire hazard, replace fuses only with those of the same type and rating. <hr/> <p>Disconnect the power cord from the ARABELLA. Remove the fuse holder by pressing down on the tab and pulling the holder out. Replace the fuse with a T 2.0 AH 250 V fuse, and push the holder back in.</p>

6.3 Initial assembly and repacking

6.3.1 Inspecting the contents

Immediately after opening all cartons, inspect the contents for damage or missing items. If the contents are damaged, contact the shipping company directly. HAMILTON MEDICAL is not responsible for shipping damages. If you discover missing items, contact your HAMILTON MEDICAL representative or ARABELLA system distributor representative.

6.3.2 Mounting the Monitoring Gas Mixer to the stand

Assemble the stand as described in the instructions included with the stand. Make sure the Monitoring Gas Mixer is firmly attached to the stand before use.

6.3.3 Repacking

If you must ship the Monitoring Gas Mixer, use the original packing materials. If these materials are not available, contact your HAMILTON MEDICAL representative for replacement materials. The warranty on the Monitoring Gas Mixer is void if it is shipped in an unauthorized carton.

A Specifications

<p>Controls</p> <p>Flow</p> <p>Oxygen</p>	<p>Range: 0 to 10 l/min, ATPD Resolution: 0.5 l/min for 1 to 10 l/min Accuracy: ± 0.3 l/min Trigger delay time: None</p> <p>Range: 21 to 100% Resolution: Not applicable Accuracy: $\pm 3\%$</p>
<p>Patient monitoring</p> <p>NCPAP</p> <p>Oxygen</p> <p>Autodimming display</p>	<p>Range: 0 to 12 cmH₂O, ATPD Resolution: 1 cmH₂O Accuracy: ± 1 cmH₂O</p> <p>Range: 21 to 100% Resolution: 1% Accuracy: $\pm 2\%$</p>
<p>Alarms</p> <p>High pressure</p> <p>Low pressure</p>	<p>Range: 0 to 12 cmH₂O (ls set to measured value at time of alarm setting +3 cmH₂O) Resolution: 1 cmH₂O</p> <p>Range: 0 to 12 cmH₂O (ls set to measured value at time of alarm setting -2 cmH₂O) Resolution: 1 cmH₂O</p>

<p>High and Low oxygen</p> <p>Low hazard</p> <p>Oxygen cell defective</p>	<p>Range: 18 to 101% (Are set to measured value at time of alarm setting $\pm 5\%$)</p> <p>Resolution: 1%</p> <p>Range: 18% FiO₂</p> <p>Resolution: Not applicable</p> <p>< 5% FiO₂</p> <p>Resolution: Not applicable</p>
<p>Input oxygen and air supplies</p>	<p>Range: 2 to 4.8 bar / 30 to 70 psig / 207 to 483 kPa</p> <p>Maximum differential pressure: 1.38 bar / 20 psig / 138 kPa</p>
<p>Electrical</p> <p>Input power</p> <p>Fuses (2)</p>	<p>100 to 125 V ~; 50/60 Hz; 0.25 A</p> <p>200 to 240 V ~; 50/60 Hz, 0.2 A</p> <p>T 2.0 AH 250 V</p>
<p>Size of Monitoring Gas Mixer</p> <p>Dimensions (W x H x D)</p> <p>Weight</p>	<p>210 x 175 x 145 mm (8.3 x 6.9 x 5.7 in.)</p> <p>6.1 kg (13.5 lb)</p>
<p>Environmental</p> <p>Temperature</p> <p>Atmospheric pressure</p> <p>Alarm volume</p>	<p>Operating: 10 to 40 °C at 0 to 75% relative humidity, noncondensing</p> <p>Storage: -10 to 60 °C at 0 to 75% relative humidity, noncondensing</p> <p>Operating/storage: 700 to 1060 hPa (mbar)</p> <p>51.5 dB(A)</p>
<p>Patient pressure relief valve</p>	<p>Type: Electronic pop-off</p> <p>Opening pressure: 10 cmH₂O ± 1 cmH₂O</p>

Patient overpressure valve	Type: Mechanical Opening pressure: 150 cmH ₂ O ±10 cmH ₂ O
Maximum flow	100 l/min STPD
Measuring and display devices	Pressure measurements: Type: Solid-state Sensing position: Inside Monitoring Gas Mixer Measurement: Delivered patient pressure Oxygen measurements: Type: Galvanic cell Sensing position: Inside Monitoring Gas Mixer Measurement: Delivered oxygen concentration
Auxiliary outlet	Gas outlet port with check valve

A.1 Warranty

HAMILTON MEDICAL AG, warrants this product to be free from defects in construction, material and workmanship for a period of one (1) year from the date of original delivery to buyer when operated properly under conditions of normal use for which the product was intended. This twelve (12) month warranty does not extend to expendable items such as the Delivery Circuit, Universal Generator with Prongs, and Caps, which are warranted to be free of defects only at the time of original delivery.

HAMILTON MEDICAL AG will, at its option, either repair or replace any defective product, as above defined, which is reported within seventy-two (72) hours of occurrence during the warranty period. Such defective products must be returned to HAMILTON MEDICAL AG in the original carton with freight charges prepaid. HAMILTON MEDICAL AG shall be responsible for repairs to, or replacement of, such defective product only.

LIMITATIONS ON AND DISCLAIMER OF WARRANTIES:

HAMILTON MEDICAL AG shall be relieved of any liability under this warranty if:

- a. the product has not been used in accordance with manufacturer's instructions;
- b. no evidence is present that the occurrence of damage/repair is within the certified warranty period;
- c. the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product's purchase date;
- d. regular periodic maintenance and service is not performed;
- e. repairs are made by other than authorized HAMILTON MEDICAL AG personnel;

-
- f. the product has been subject to abuse, misuse, negligence or accident;
 - g. the product has been mechanically or electronically altered without specific written authorization from HAMILTON MEDICAL AG

The warranty described in this Agreement is in lieu of all other warranties. THE PARTIES AGREE THAT THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, ARE EXCLUDED FROM THIS AGREEMENT.

Except as stated above, HAMILTON MEDICAL AG SHALL NOT BE LIABLE FOR ANY DAMAGES, CLAIMS OR LIABILITIES INCLUDING, BUT NOT LIMITED TO, PERSONAL BODILY INJURY, OR INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES.

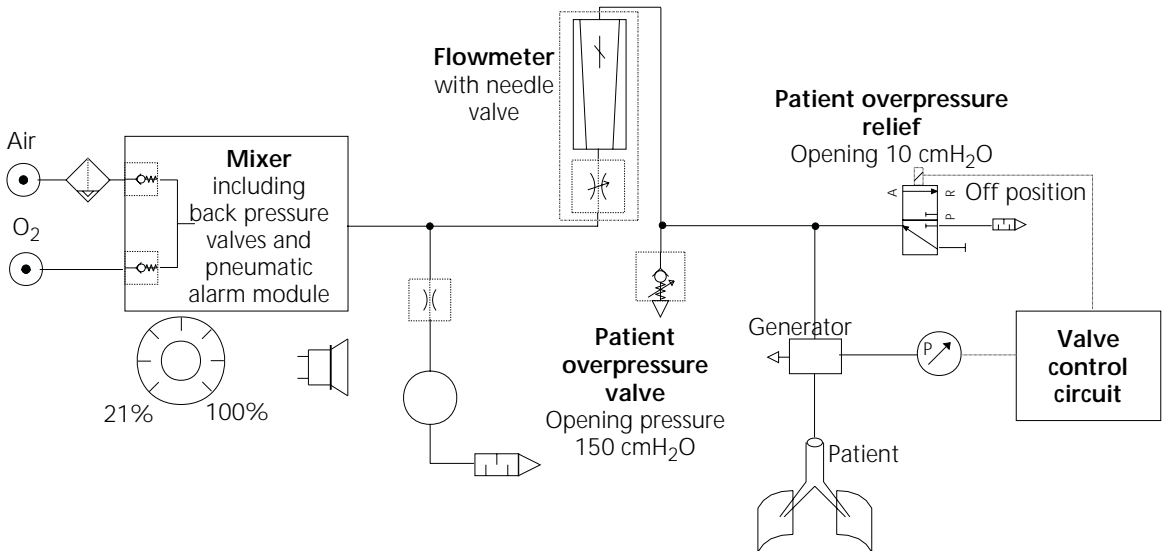
Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty.

Any person may not vary the terms of this Limited Warranty, whether or not purporting to represent or act on behalf of HAMILTON MEDICAL AG.

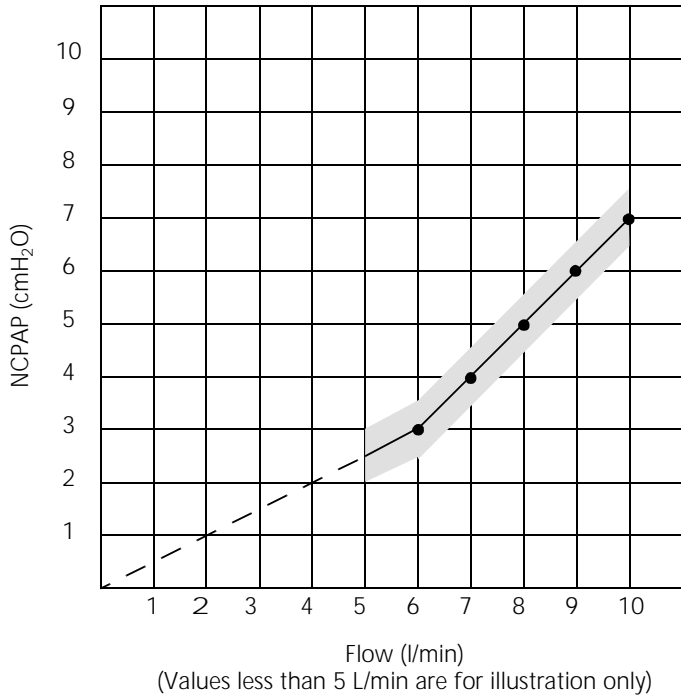
SERVICE

To obtain service under this Limited Warranty, claimant must promptly notify HAMILTON MEDICAL AG of the nature of the problem and the serial number of the device. If HAMILTON MEDICAL AG determines that the repair is required under this Limited Warranty, the defective device or respective part must be returned to HAMILTON MEDICAL AG or an authorized service center. Item must be properly packaged, insured and shipped to HAMILTON MEDICAL AG postage/freight paid by claimant.

B Pneumatic diagram



C Pressure-flow nomogram



D Two-person setup before endotracheal extubation

Use this two-person technique to place and initiate the ARABELLA system before endotracheal extubation.

1. Assemble the ARABELLA Monitoring Gas Mixer and Delivery Circuit as described in Section 2.
2. Select the appropriate size Cap to comfortably fit the infant. Place the Cap on the infant's head, ensuring that the two ties (tan and colored) are in line with the bridge of the nose.
3. Using the ARABELLA KNOSOMETER, select the correct size prongs to fit the nares. Position the prongs into the Universal Generator. Connect the Generator to the appropriate Delivery Circuit.

Person one:

4. Turn the Monitoring Gas Mixer on. Set the oxygen control to the prescribed FiO_2 . Set the flow control to the appropriate flow rate for the desired CPAP (approximately 8 l/min of flow should deliver 5 cmH_2O CPAP). Occlude the prongs, and check the NCPAP pressure on the Monitoring Gas Mixer's pressure.
5. Before starting NCPAP, suction the infant's oral and nasal passages. Support the back of the infant's head with one hand. Using the other hand, insert the NCPAP prongs into the infant's nose.

Person two:

6. Prepare the infant for extubation per hospital policy and procedure. Suction the endotracheal tube before removal. Securely hold the endotracheal tube in position and loosen the securing tape. Make sure the Generator is in the nares, and that the Monitoring Gas Mixer is on and delivering the flow to achieve the desired NCPAP. Remove the endotracheal tube.
7. Secure the proximal pressure line to the top of the Cap using the first tie on the Cap. Open the VELCRO tabs on the side of the Cap, and attach the blue foam straps. Secure

the foam straps to the Cap by closing the VELCRO tabs. Tie the extended expiratory limb and the clear proximal pressure line to the Cap with the colored tie at the back of the Cap. Per setup guidelines, adjust the expiratory limb to prevent stress on the septum.

8. Set the Monitoring Gas Mixer alarms.
9. Follow the hospital guidelines for monitoring and documentation of NCPAP.

E Parts and accessories

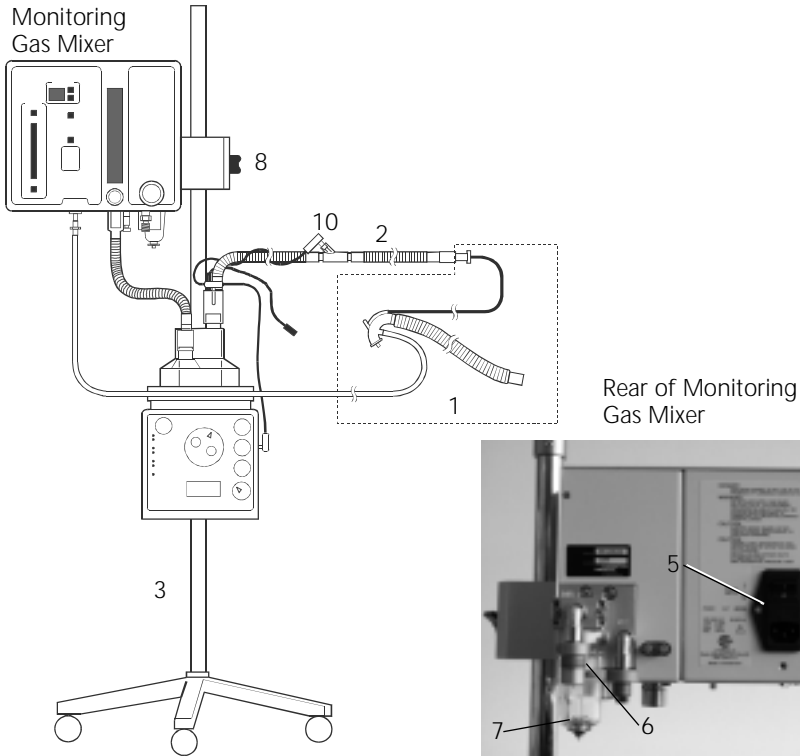


Table E-1. ARABELLA system parts and accessories (US)

Item no.	Part no.	Description
1	33201	Universal Generator set, box of 10 Includes: Generator with 1 each small, medium, large, and extra large prongs 72 in. (1.82 m) proximal pressure line 36 in. (0.91 m) compressed expiratory limb KNOSOMETER prong sizing guide

Table E-1. ARABELLA system parts and accessories (US) (continued)

Item no.	Part no.	Description
2	33076	Delivery Circuit, heated-wire, 16 V, box of 20 (For use with these humidifiers: AnaMed Medical, Inc., "NIC" Heated System, PN 4003 and Hudson RCI ConchaTherm III Plus, PN 380-90)
	33078	Delivery Circuit, heated-wire, 21 V, box of 20 (For use with these humidifiers: Fisher & Paykel MR630 and MR730; Hudson RCI ConchaTherm III Plus, PN 380-88 and ConchaTherm IV, PN 400-00; and AnaMed Medical, Inc., "NIC" Heated System, PN 4009)
	33077	Delivery Circuit, heated-wire, 28 V, box of 20 (For use with Marquest Medical Products, Inc., SCT 3000 humidifier)
3	31201	Stand, five-leg, ARABELLA
4	33101	Cap, size 1 (S/small), box of 10*
	33102	Cap, size 2 (M/medium), box of 10*
	33103	Cap, size 3 (L/large), box of 10*
	33104	Cap, size 4 (XL/extra large), box of 10*
	33105	Cap, size 5 (XXL/extra extra large), box of 5*
6	279676	Microfilter, gas supply, 5 μ m
7	279729	Bowl, gas supply filter assembly
8	235336	Pole clamp, 15 mm - 25 mm (For use when mounting a humidifier with a 30 mm parallel channel bracket, such as the MR730)
10	279226	Temperature probe, dual, 1.3 m (51.2 in.)

*Not shown

**Table E-2. ARABELLA system parts and accessories
(non-US)**

Item no.	Part no.	Description
1	R33201	Universal Generator set, box of 10 Includes: Generator with 1 each small, medium, large, and extra large prongs 72 in. (1.82 m) proximal pressure line 36 in. (0.91 m) compressed expiratory limb KNOSOMETER prong sizing guide
2	R33076	Delivery Circuit, heated-wire, 16 V, box of 20 (For use with these humidifiers: AnaMed Medical, Inc., "NIC" Heated System, PN 4003 and Hudson RCI ConchaTherm III Plus, PN 380-90)
	R33078	Delivery Circuit, heated-wire, 21 V, box of 20 (For use with these humidifiers: Fisher & Paykel MR630 and MR730; Hudson RCI ConchaTherm III Plus, PN 380-88 and ConchaTherm IV, PN 400-00; and AnaMed Medical, Inc., "NIC" Heated System, PN 4009)
	R33077	Delivery Circuit, heated-wire, 28 V, box of 20 (For use with Marquest Medical Products, Inc., SCT 3000 humidifier)
3	235751	Stand, five-leg, ARABELLA
4	R33101	Cap, size 1 (S/small), box of 10*
	R33102	Cap, size 2 (M/medium), box of 10*
	R33103	Cap, size 3 (L/large), box of 10*
	R33104	Cap, size 4 (XL/extra large), box of 10*
	R33105	Cap, size 5 (XXL/extra extra large), box of 5*
5	363076	Fuse, T 2.0 A H 250 V (2 required)
6	279676	Microfilter, gas supply, 5 µm
7	279729	Bowl, gas supply filter assembly

*Not shown

**Table E-2. ARABELLA system parts and accessories
(non-US) (continued)**

Item no.	Part no.	Description
8	235336	Pole clamp, 15 mm - 25 mm (For use when mounting a humidifier with a 30 mm parallel channel bracket, such as the MR730)
9	281185	Electrical adapter, MR730 humidifier to ARABELLA Delivery Circuit*
10	279226	Temperature probe, dual, 1.3 m (51.2 in.)
11	235787	Compressor, for ARABELLA, 230 V ac, 50 Hz (14 l/min)*

*Not shown

Accessory flowmeter for Monitoring Gas Mixer

A secondary 50-psi outlet located at the base of the Monitoring Gas Mixer's blender lets you attach an additional flowmeter for delivery of low-flow oxygen therapy, blended gas delivery for aerosolized medication, and blended gas delivery for resuscitation devices.

Assemble the flowmeter to the Monitoring Gas Mixer as follows, referring to Figure F-1.

1. Connect part **C** to part **B**.
2. Attach the combined part **B/C** to the back of the flowmeter **A**.
3. Connect the nut on part **C** to the base of the ARABELLA Monitoring Gas Mixer check valve. Hand-tighten nut.
4. Make sure there are no leaks in the assembled parts and that all parts are securely attached to the Monitoring Gas Mixer.

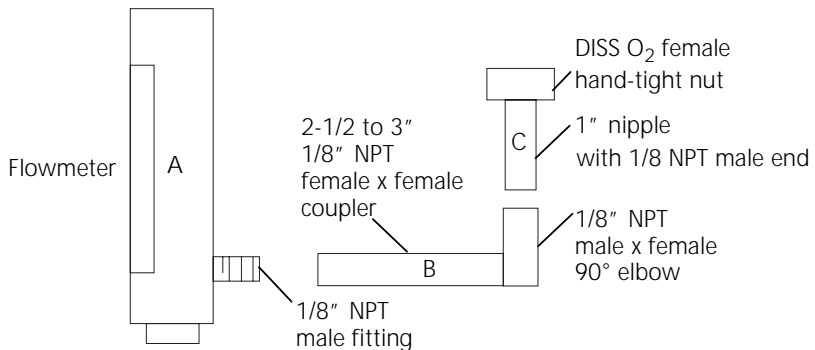


Figure F-1. Installing a flowmeter

